UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|------------------------------|----------------------|---------------------|------------------|
| 10/618,994 | 07/14/2003 | Scott Cunningham | 2848 | 5963 |
| 50855 Tyco Healthcar | 7590 09/18/200 e Group LP | 8 | EXAMINER | |
| 60 MIDDLETC | OWN AVENUE | | YABUT, DIANE D | |
| NORTH HAVEN, CT 06473 | | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/18/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) |
|--|--|--|
| | 10/618,994 | CUNNINGHAM ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | DIANE YABUT | 3734 |
| The MAILING DATE of this communication appeariod for Reply | ppears on the cover sheet with the | correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perio - Failure to reply within the set or extended period for reply will, by statu. Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATIO 1.136(a). In no event, however, may a reply be tild will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE | N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133). |
| Status | | |
| 1) ☐ Responsive to communication(s) filed on 21. 2a) ☐ This action is FINAL . 2b) ☐ Th. 3) ☐ Since this application is in condition for allow closed in accordance with the practice under | is action is non-final. ance except for formal matters, pr | |
| Disposition of Claims | | |
| 4) ☐ Claim(s) 1,2,5-17 and 20-22 is/are pending in 4a) Of the above claim(s) is/are withdr 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1,2,5-17 and 20-22 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and application Papers | rawn from consideration. | |
| 9) The specification is objected to by the Examir | ner | |
| 10) The drawing(s) filed on is/are: a) according a deplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examination is objected to by the Examination is objected to by the Examination is objected. | ccepted or b) objected to by the e drawing(s) be held in abeyance. Se ection is required if the drawing(s) is ob | e 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority document a. ☐ Certified copies of the priority document a. ☐ Copies of the certified copies of the priority document application from the International Bure * See the attached detailed Office action for a list | nts have been received. nts have been received in Applicat iority documents have been receiv au (PCT Rule 17.2(a)). | ion No ed in this National Stage |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other: | ate |

Application/Control Number: 10/618,994 Page 2

Art Unit: 3734

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/21/2008 has been entered.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-2, 5-14, and 21-22 are rejected under 35 U.S.C. 112, second paragraph. Claims 1, 5, 8, and 14 recite the limitation "the needle end": lines 5, 1, 13, and 16 of claim 1; line 3 of claim 5; line 3 of claim 8; line 2 of claim 14. It is unclear which needle end (first or second) is being claimed. Claim 12 recites the limitation "the linear cutting edge" in line 2. There is insufficient antecedent basis for these limitations in the claims.

Art Unit: 3734

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35
U.S.C. 102 that form the basis for the rejections under this section made in this
Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 1-2, 5-6, 8, 10, 12-17, and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by **McGregor et al.** (U.S. Patent No. 5,002,564).

Claims 1-2, 5-6, 8, 10, 12-17, and 21-22: McGregor et al. disclose a surgical needle, which comprises an elongated needle body curved along a longitudinal y axis, and comprising x and z axes transverse to the y-axis, the elongated needle body including a central shaft 25 and having a first end 30 for attachment to a suture and a second needle end for penetrating tissue, the needle end including planar lower 14 and upper 16 opposed surfaces and single side surfaces 20a-b extending continuously between the lower and upper surfaces and contiguous therewith, the upper surface and side surfaces intersecting to define opposed first and second generally arcuate side cutting edges 16 or 18 extending to a pointed tip 12, the lower surface extending to a linear third cutting edge T defined at the intersection of the side surfaces and proximal of the pointed tip, the third cutting edge extending in oblique relation relative to the longitudinal axis of the needle body to terminate at the pointed tip, the third cutting edge intersecting the upper planar surface at an angle ranging from 15 to 30 degrees relative to the

Application/Control Number: 10/618,994 Page 4

Art Unit: 3734

longitudinal axis (col. 2, lines 58-65), the second needle end defining a maximum dimension inclusive of the first and second cutting edges greater than a corresponding maximum dimension of the central shaft, the second needle end having a transition area, a proximal portion of the needle end disposed proximally of the transition area including a first length having a trapezoidal transverse cross-sectional dimension length (Figure 6) inclusive of the first and second cutting edges and a distal portion of the needle end disposed distally of the transition area including a second length having a triangular transverse cross-sectional dimension (Figure 5) inclusive of the first and second cutting edges, the first length being longer than the second length, at least a portion of the first length having a diameter that decreases distally towards the needle end, and at least a portion of the first length having a diameter that decreases proximally towards the central shaft of the needle body (see Figures 1-8).

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 3734

7. Claims 7, 9, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over by **McGregor et al.** (U.S. Patent No. **5,002,564**).

Claims 7, 9, and 20: McGregor et al. do not expressly disclose the first width or width of the trapezoidal cross section or maximum dimension of the second needled end being not less than about 1.5 times the shaft width, or the first height, or height of the trapezoidal cross section being not greater than about 0.5 times the shaft height.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the first width being not less than about 1.5 times the shaft width, or the first height being not greater than about 0.5 times the shaft height, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Response to Arguments

8. Applicant's arguments with respect to claims 1-2, 5-17, and 20-22 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 3734

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/ Examiner, Art Unit 3734

/Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3731